

**Subject:** Q140229/S001

**Date:** Monday, March 9, 2015 at 11:38:11 AM Pacific Daylight Time

**From:** Shukla, Sunita

**To:** Nussbaum, Robert, Chen, Flavia, Koenig, Barbara

**CC:** 'Q140229-S001@docs.fda.gov'

Dear Dr. Nussbaum,

I have reserved a telecon date of 4/10/15 from 11-12 PM ET. Please confirm this date/time.

The call-in information is as follows: Dial in number: 1-877-411-0221, Participant Pass Code: 30253990.

Sunita Shukla, MPH, Ph.D.

Scientific Reviewer

Division of Chemistry and Toxicology Devices

Office of In Vitro Diagnostics and Radiological Health (OIR)

Food and Drug Administration

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**From:** Nussbaum, Robert [mailto:Robert.Nussbaum@ucsf.edu]

**Sent:** Monday, March 09, 2015 2:13 PM

**To:** Shukla, Sunita; Chen, Flavia; Koenig, Barbara

**Cc:** 'Q140229-S001@docs.fda.gov'

**Subject:** Re: Q140229/S001

**Importance:** High

Dear Dr. Shukla: I will be in Kansas City (CDT) and can talk from 11-12 EDT (10-11 CDT).

Robert L. Nussbaum, MD, FACP,FACMG

Chief, Division of Genomic Medicine

Department of Medicine & UCSF Institute

for Human Genetics

Box 0794

513 Parnassus Ave. HSE901E

San Francisco, CA 94143

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**From:** <Shukla>, Sunita Shukla <[Sunita.Shukla@fda.hhs.gov](mailto:Sunita.Shukla@fda.hhs.gov)>  
**Date:** Monday, March 9, 2015 at 6:48 AM  
**To:** Robert Nussbaum <[robert.nussbaum@ucsf.edu](mailto:robert.nussbaum@ucsf.edu)>  
**Cc:** "'[Q140229-S001@docs.fda.gov](mailto:Q140229-S001@docs.fda.gov)'" <[Q140229-S001@docs.fda.gov](mailto:Q140229-S001@docs.fda.gov)>  
**Subject:** RE: Q140229/S001

Dear Dr. Nussbaum,

In order to reserve a time for your requested teleconference, please let me know if the proposed date/time below works (on 4/10). If that date doesn't work, the next available dates will be during the week of 4/20 since I'll be out of the office the week of 4/13. Thank you, Sunita

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**From:** Shukla, Sunita  
**Sent:** Friday, March 06, 2015 2:44 PM  
**To:** 'Nussbaum, Robert'  
**Cc:** [Q140229-S001@docs.fda.gov](mailto:Q140229-S001@docs.fda.gov)  
**Subject:** RE: Q140229/S001

Would Friday April 10<sup>th</sup> work for you? We have 11-12 PM or 3-4 PM ET available.

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**From:** Nussbaum, Robert [<mailto:Robert.Nussbaum@ucsf.edu>]

**Sent:** Friday, March 06, 2015 2:43 PM  
**To:** Shukla, Sunita  
**Subject:** Re: Q140229/S001

I will be on an airplane at that time and not able to participate.

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**From:** <Shukla>, Sunita <[Sunita.Shukla@fda.hhs.gov](mailto:Sunita.Shukla@fda.hhs.gov)>  
**Date:** Friday, March 6, 2015 at 11:41 AM  
**To:** Robert Nussbaum <[robert.nussbaum@ucsf.edu](mailto:robert.nussbaum@ucsf.edu)>  
**Cc:** "[Q140229-S001@docs.fda.gov](mailto:Q140229-S001@docs.fda.gov)" <[Q140229-S001@docs.fda.gov](mailto:Q140229-S001@docs.fda.gov)>  
**Subject:** RE: Q140229/S001

I'm sorry, I meant to say the 4/8/15 telecon date below.

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**From:** Shukla, Sunita  
**Sent:** Friday, March 06, 2015 2:40 PM  
**To:** 'Nussbaum, Robert'  
**Subject:** RE: Q140229/S001

I will also be on the call, including other potential FDA participants.

In my previous email, please let me know if the 4/6/15 date and time is suitable for you regarding your specific submission noted above and discussion regarding the 2 questions you had associated with it. Thank you, Sunita

Sunita Shukla, MPH, Ph.D.  
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**From:** Nussbaum, Robert [<mailto:Robert.Nussbaum@ucsf.edu>]  
**Sent:** Friday, March 06, 2015 2:38 PM  
**To:** Shukla, Sunita  
**Subject:** Re: Q140229/S001

I think David Litwack will be attending the call for the FDA today.

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**From:** <Shukla>, Sunita <[Sunita.Shukla@fda.hhs.gov](mailto:Sunita.Shukla@fda.hhs.gov)>  
**Date:** Friday, March 6, 2015 at 11:27 AM  
**To:** Robert Nussbaum <[robert.nussbaum@ucsf.edu](mailto:robert.nussbaum@ucsf.edu)>  
**Cc:** "Chen, Flavia" <[Flavia.Chen@ucsf.edu](mailto:Flavia.Chen@ucsf.edu)>, Tiina Urv <[urvtiin@mail.nih.gov](mailto:urvtiin@mail.nih.gov)>, Anastasia Wise <[anastasia.wise@nih.gov](mailto:anastasia.wise@nih.gov)>, "Q140229-S001@docs.fda.gov" <[Q140229-S001@docs.fda.gov](mailto:Q140229-S001@docs.fda.gov)>  
**Subject:** RE: Q140229/S001

Thank you. Please let me know about the telecon date at your earliest convenience.

Sunita Shukla, MPH, Ph.D.  
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**From:** Nussbaum, Robert [<mailto:Robert.Nussbaum@ucsf.edu>]  
**Sent:** Friday, March 06, 2015 2:19 PM  
**To:** Shukla, Sunita  
**Cc:** Chen, Flavia; Urv, Tiina K (NIH); Wise, Anastasia L (NIH)  
**Subject:** Re: Q140229/S001

I give permission for you to speak about our submission to the other NSIGHT investigators on the conference call today. I had already given such permission to Dr. Kelm.

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**From:** <Shukla>, Sunita <[Sunita.Shukla@fda.hhs.gov](mailto:Sunita.Shukla@fda.hhs.gov)>  
**Date:** Friday, March 6, 2015 at 11:12 AM  
**To:** Robert Nussbaum <[robert.nussbaum@ucsf.edu](mailto:robert.nussbaum@ucsf.edu)>  
**Subject:** Q140229/S001

Dear Dr. Nussbaum,

Thank you for the additional information you have provided in the above noted submission. Since Dr. Kelm has been promoted to the cardio-renal branch chief in our Division, I will be the lead reviewer for this file. Please note that I will be working with Dr. Kelm closely on this pre-submission.

I also wanted to email you regarding a potential teleconference date/time of Wednesday April 8<sup>th</sup> from 1-2 PM ET. Please note that you will be receiving written feedback at least 4 business days prior to the telecon date. Please confirm if this date/time works for you and I will send a call-in number. Thank you, Sunita

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